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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/501,570 | 09/27/2004 | Julio Cesar Aguilar Rubido | 976-18 PCT/US | 9315 |
| 23869 | 7590 | 11/27/2006 | | |
| HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791 | | | EXAMINER PENG, BO | |
| | | | ART UNIT 1648 | PAPER NUMBER |

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

1. This Office Action is in response to the amendment filed September 11, 2006. Claims 1, 3 and 13 have been amended. Claim 21 has been cancelled. Claims 4-12 have been withdrawn as non-elected invention. Accordingly, Claims 1-20 are pending. Claims 1-3 and 13-20 are considered in this Office action.
2. The new abstract is accepted by the examiner.
3. The objection to Claim 21 **is withdrawn** in view of the Applicant's amendment.
4. The rejection of Claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, **is withdrawn** in view of the amendment to the claim.
5. The rejection of Claims 1-3 and 13-20 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement, **is withdrawn** in view of the amendment.
6. The rejection of Claims 1-3 and 13-20 under 35 U.S.C. 112, first paragraph for failing to comply with the enablement requirement, **is withdrawn** in view of Applicant's amendment.
7. The rejection of Claims 1-3 and 13-21 under 35 U.S.C. 103(a) as being obviousness over Schmitt (2000), Alpar (2001) and Isaka (2001), **is maintained** for the following reasons:
8. Applicant argues that neither Schmitt nor Alpar discloses and suggests that HBsAg in the

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formulation is an immunoenhance of other antigens. In fact, in Schmitt's multivalent vaccine formulation, the other antigens are either comparable or less immunogenic when administered in a mixture than when administered separately (Remarks, Paragraph 6, p.10 to Paragraph 2, p. 11).

9. In response to applicant's argument, the immunogenicity of HBsAg and its effect on other antigens, such as "immunoenhancement", is an inherent property of HBsAg. MPEP states "In determining whether the invention as a whole would have been obvious under 35U.S.C. 103, we must first delineate the invention as a whole. In delineating the invention as a whole, we look not only to the subject matter which is literally recited in the claim in question... but also to those properties of the subject matter which are inherent in the subject matter and are disclosed in the specification. . . Just as we look to a chemical and its properties when we examine the obviousness of a composition of matter claim, it is this invention as a whole, and not some part of it, which must be obvious under 35 U.S.C.103." *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977). (See MPEP 2141.02). Moreover "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). (See MPEP 2141.02)

10. Since HBsAg is taught and used in multivalent vaccine formulations of both Schmitt's and Isaka's, its ability to affect the immunogenicity of other antigens is disclosed by Schmitt and Isaka. Thus, the claimed invention is obvious over the combination of Schmitt, Alpar and Isaka.

Remarks

10. No claims are allowed. Accordingly, **THIS ACTION IS MADE FINAL.**

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Bo Peng, Ph.D.
November 20, 2006



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